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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/072,691

02/07/2002

Lucio Giambattista

P-5023

3218

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7590

07/22/2004

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EXAMINER

MAIORINO, ROZ

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental

Office Action Summary	Application No. 10/072,691	Applicant(s) GIAMBATTISTA ET AL.	
	Examiner Roz Maiorino	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-11, 14-21 and 24-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-11, 14-21, 24-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 4, 8, 10, 11, 14, 17, 19, 21, 21, 90-31, 33-36, 24, rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6322540 to Grabis et al.

Grabis teaches safety shield system for a needle cannula comprising a general tubular clip member 11 having a plurality of spaced laterally projecting fingers 5, a generally tubular reciprocal shield 7 including a first portion surrounding the said clip member, a second portion normally surrounding the needle cannula and a plurality of spaced axially extending inwardly opening channel shaped tracks on the inside surface of the shield receiving said laterally projecting resilient fingers of the clip member and guiding said shield axially from a first position wherein said shield second portion surrounds said needle cannula to a second position wherein said needle cannula is exposed, and a spring 6 resiliently biasing said shield axially to normally extend said shield second portion to surround said needle cannula, wherein at least one of said channel shaped tracks includes an opening which receives one of the fingers when said shield is first

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retracted to said second position and then extended to the first position by the spring and locking the shield in the first position. (figures 1-4)

2. Claims 1, 4, 8, 10, 11, 14, 17, 19, , 21, 21, 90-31, 33-36, 24 rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6162198 to Mohammad.

Mohammed teaches safety shield system for a needle cannula comprising a general tubular clip member (figures 1b, 11) having a plurality of spaced laterally projecting finger 8, a generally tubular reciprocal shield 9 including a first portion surrounding the said clip member, a second portion normally surrounding the needle cannula 1 and a plurality of spaced axially extending inwardly opening channel shaped tracks on the inside surface of the shield receiving said laterally projecting resilient fingers of the clip member and guiding said shield axially from a first position wherein said shield second portion surrounds said needle cannula to a second position wherein said needle cannula is exposed, and a spring 16 resiliently biasing said shield axially to normally extend said shield second portion to surround said needle cannula, wherein at least one of said channel shaped tracks includes an opening which receives one of the fingers when said shield is first retracted to said second position and then extended to the first position by the spring and locking the shield in the first position. (figures 1-16)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.6162198 to Mohammad.

Mohammad teaches the invention except for a clip member with plurality of radically extending ribs. However Mohammad does teach one rib that extends from the clip member, which prevents rotation of the shield relative to the clip member and guiding the shield axially.

In re Harza, 274 F.2d 669, 671, 124 USPQ 378, 380(CCPA 1960) it would have been obvious to one having ordinary skill in the art to have duplicated part for (rib on the clip member) for multiple effect.

4. Claims 1, 4-11, 14-21, 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.5201708 to Martin and further in view of US Patent NO.5385551 to Shaw.

Martin teaches safety shield system for a needle cannula comprising a general tubular clip member 200 having a plurality of spaced laterally profiting fingers 52, a generally tubular reciprocal shield including a first portion surrounding the said clip member, a second portion normally surrounding the needle cannula 92 and a plurality of spaced axially extending inwardly opening channel shaped tracks on the inside surface of the shield receiving said laterally projecting resilient fingers of the clip member and guiding said shield axially from a first position wherein said shield second portion surrounds

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said needle cannula 92 to a second position wherein said needle cannula 92 is exposed, and a spring 50 resiliently biasing said shield axially to normally extend said shield second portion to surround said needle cannula, wherein at least one of said channel shaped tracks includes an opening which receives one of the fingers when said shield is first retracted to said second position and then extended to the first position by the spring and locking the shield in the first position.(figure 3)

Martine apparatus however is reusable unlike the present application, Shaw teaches a nonreusable medical device.

Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to have made Martin's apparatus non-reusable, because it is well known in the art that any device that reaches the drug using community such a needle should be made non reusable to help reduce the spread of AIDS. (Col. 1, lines 15-25)

Response to Arguments

5. Applicant's arguments with respect to claims 1, 4-11, 14-21, 24-36 have been considered but are moot in view of the new ground(s) of rejection.

6. Applicant's arguments filed 2-3-2004 have been fully considered but they are not persuasive. Applicant alleges Martin does not teach the free end portion of the resilient finger pass freely over the opening defined through the sidewall of the shield. However in figure 3 Martin does teach the fingers passing through opening in the shield. If applicant is claiming non-reusability of the syringe makes it unique, he/she should claim the locking mechanism in which makes the syringe non-reusable.

7. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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